**SECTION 5** **510K SUMMARY**

## 510(k) Summary for NephroMax™ High Pressure Balloon Dilatation Catheter

SEP 18 2012

### A. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01756

### B. Contact

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or

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### C. Device Name

Trade name: NephroMax™ High Pressure Balloon Dilatation Catheter
Common/usual name: Catheter, Nephrostomy
Classification Name: LJE – Catheter, Nephrostomy
Pre-Amendment

### D. Predicate Device

Trade name: Nephrostomy Balloon Dilatation Catheter
Common/usual name: Catheter, Nephrostomy
Classification Name: LJE – Catheter, Nephrostomy
Pre-Amendment

Premarket Notification: Boston Scientific, K952968

### E. Device Description

The NephroMax Balloon Catheter, styled after the Gruntzig technique, is a multiple lumen catheter with a dilatation balloon mounted at the distal tip. Provided with the balloon catheter is a 24F (8 mm) or 30F (10 mm) renal sheath. Dilatation balloon catheters are used to exert radial force to dilate nephrostomy tracts. The balloon features a silicone coating to reduce friction between the balloon surface and renal sheath.

### F. Intended Use

The NephroMax Balloon Catheters are recommended for dilatation of the nephrostomy tract.

**G. Technological Characteristics**

The NephroMax Balloon Catheter has the same technological characteristics and fundamental multi-lumen balloon dilatation catheter design as the predicate device. The proposed NephroMax Balloon Catheter is available in four configurations with three balloon sizes.

**H. Substantial Equivalence**

A direct comparison of key characteristics demonstrates that the proposed balloon dilatation catheter is substantially equivalent to the predicate device in terms of intended use, technological characteristics, and performance characteristics. The NephroMax Balloon Catheter is as safe, as effective, and performs as well as the predicate device.

**I. Performance Testing (Bench Evaluation)**

Boston Scientific has conducted performance testing with samples aged at T=0 and T=7 months accelerated aging in support of the balloon design change and additional size configurations. The following testing was completed to evaluate the effects of the design change and sizes:

- Effective Working Length
- Catheter Tip Length/ RO Marker Location
- Deflation Time
- Balloon Diameter/Length at Rated Burst Pressure
- Balloon Compliance
- Multiple Inflation
- Balloon Burst
- Proximal Balloon Bond Tensile
- Balloon Protector Removal Force
- Guidewire Passability

The results of the performance testing demonstrate equivalence of the NephroMax Balloon Catheter to the predicate balloon dilatation catheter. The NephroMax Balloon Catheters are considered safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2012

Ms. Lauren Anderson
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

Re: K121614
Trade/Device Name: Nephromax™ High Pressure Balloon Dilatation Catheter
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LJE
Dated: July 30, 2012
Received: August 22, 2012

Dear Ms. Anderson :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**SECTION 4** **INDICATIONS FOR USE**

## Indications for Use Statement

| | |
|---|---|
| **510(k) Number** | ~~To be determined.~~ K121614 |
| **Device Name** | Nephromax™ High Pressure Balloon Dilatation Catheter |
| **Indications For Use** | The Nephromax™ High Pressure Balloon Dilatation Catheters are recommended for dilatation of the nephrostomy tract. |

Prescription Use __X____ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121614